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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/815,242	03/21/2001	Robert Haselbeck	ELITRA.011A	7191

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EXAMINER	
GIBBS, TERRA C	
ART UNIT	PAPER NUMBER
1635	

DATE MAILED: 12/14/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

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Office Action Summary	Application No.	Applicant(s)	
	09/815,242	HASELBECK ET AL.	
	Examiner	Art Unit	
	Terra C. Gibbs	1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 September 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *12,31,45-69,77-87,89-96,100,101,103 and 104* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *12,85,86 and 89-96* is/are allowed.

6)☒ Claim(s) *12,31,45-69,77-84,87,89-96 and 101* is/are rejected.

7)☒ Claim(s) *100, 103, and 104* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

This Office Action is a response to Applicant's Appeal Brief filed September 19, 2006.

Claims 12, 31, 45-69, 77-87, 89-96, 100, 101, 103, and 104 are pending in the instant application.

It is noted that after careful reconsideration of the claims, the Examiner has decided to reopen prosecution of the instant application. For further explanation, see discussion below under "Withdrawal of Finality". This decision was made after an Appeals Conference, conducted between the Examiner, her Primary Examiner, Sean McGarry, and her Supervisor, James Schultz, on December 7, 2006.

It is noted that in Applicant's election filed March 4, 2003, Applicants elected SEQ ID NO: 1463 as the antisense sequence complementary to the *yphC gene*, SEQ ID NO: 12600 as the *yphC* gene product (polypeptide), and SEQ ID NO: 4228 as the *yphC* nucleic acid encoding the gene product (polypeptide). It is further noted that SEQ ID NOs. 521, 1390, 1845, 2782, 3283, 3966, 6154, 6592, 6872, 7273, 7857, 8502, 9420, and 9605 as recited in claims 77, 87, 100, and 104, are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement on March 4, 2003.

Claims 12, 31, 45-69, 77-87, 89-96, 100, 101, 103, and 104 have been examined on the merits, to the extent that they read on the elected invention.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Appeal Brief

Applicant's Appeal Brief, filed September 19, 2006 is acknowledged and has been fully considered by the Examiner.

Withdrawal of Finality

Applicants received a Final Office Action mailed October 19, 2005. After careful reconsideration of the claims, the Examiner has decided to reopen prosecution of the instant application because the Examiner did not raise 35 U.S.C. 112 first and second paragraph issues earlier during prosecution.

A new Non-Final Office Action on the merits follows:

Double Patenting

In the previous Office Action mailed October 19, 2005, claims 12, 31, 45-69, 71-87, 89-96, 100, 101, 103 and 104 were rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-6, 9 and 10 of U.S. Patent No. 6,720,139 ('139). **This rejection is withdrawn** in view of the arguments found in Applicant's Appeal Brief, filed September 19, 2006. Specifically, the Examiner is withdrawing this rejection in view of Applicant's arguments that the pending claims differ from the '139 patent claims by providing descriptions of sequences. It is

noted that the '139 patent claims a genus, while the claims of the instant application claim a species. While the presence of a species anticipates a genus, a genus does not *per se* anticipate or make obvious a species covered by the genus, as is the case in the instant rejection.

Claim Rejections - 35 USC § 112

In the previous Office Action mailed October 19, 2005, claims 78-84 were rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. **This rejection is withdrawn** in view of the new 35 U.S.C. 112, first paragraph rejection as detailed below:

Specification

The specification is objected to because the specification at pages 5, 76, 90, 127, and 185 contain embedded hyperlinks and/or other forms of browser-executable code that are impermissible and must be deleted. The attempt to incorporate subject matter into the patent application by reference to a hyperlink and/or other forms of browser-executable code is considered to be an improper incorporation by reference. See MPEP 608.01(p), paragraph I regarding incorporation by reference. Furthermore, if the application should issue and be placed on the Office web page, the URL may be interpreted as a valid HTML code and become a live web link, transferring a user to a commercial web site. Office policy does not permit the Office to link to any commercial site because the Office exercises no control over the organization, views or accuracy of

the information contained on these outside sites.

The above is an example and is not intended to indicate that the Examiner has made an exhaustive review of the application. Applicant should remove all embedded hyperlinks for any response to this action to be considered fully responsive.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 57-69, 78-84, and 87 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 57 is indefinite because it recites, "The method of claim 31, **wherein said gene product**". It is unclear which gene product the claim is referring to since claim 31 recites five different gene products. For example, claim 31 recites, (1) a gene product encoded by a nucleic acid having at least 70% nucleotide sequence identity to a nucleic acid encoding a gene product whose expression is inhibited by SEQ ID NO:1463; (2) a gene product having at least 25% amino acid identity to a gene product whose expression is inhibited by SEQ ID NO:1463; (3) a gene product encoded by a nucleic acid which hybridizes to SEQ ID NO:1463 under stringent conditions; (4) a gene product encoded by a nucleic acid which hybridizes to SEQ ID NO:1463 under moderate conditions; and (5) a gene product whose activity may be complemented by a gene

product whose activity is inhibited by SEQ ID NO:1463. Claims 58-69 are included in this rejection because of their dependency therein.

Claim 77 is indefinite because it recites, "The method of claim 31, **wherein said nucleic acid encoding said gene product**". It is unclear which nucleic acid encoding said gene product the claim is referring to since claim 31 recites three different nucleic acids encoding gene products. For example, claim 31 recites (1) a gene product encoded by a nucleic acid having at least 70% nucleotide sequence identity to a nucleic acid encoding a gene product whose expression is inhibited by SEQ ID NO:1463; (2) a gene product encoded by a nucleic acid which hybridizes to SEQ ID NO:1463 under stringent conditions; and (3) a gene product encoded by a nucleic acid which hybridizes to SEQ ID NO:1463 under moderate stringent conditions.

Claim 78 is indefinite because it recites, "The method of claim 31, **wherein said antisense nucleic acid**". It is unclear which antisense nucleic acid the claim is referring to since claim 31 recites five different antisense nucleic acids. For example, claim 31 recites (1) an antisense complementary to a gene product encoded by a nucleic acid having at least 70% nucleotide sequence identity to a nucleic acid encoding a gene product whose expression is inhibited by SEQ ID NO:1463; (2) an antisense complementary to a gene product having at least 25% amino acid identity to a gene product whose expression is inhibited by SEQ ID NO:1463; (3) an antisense complementary to a gene product encoded by a nucleic acid which hybridizes to SEQ ID NO:1463 under stringent conditions; (4) an antisense complementary to a gene product encoded by a nucleic acid which hybridizes to SEQ ID NO:1463 under

moderate conditions; or (5) an antisense complementary to a gene product whose activity may be complemented by a gene product whose activity is inhibited by SEQ ID NO:1463. Claims 79-84 are included in this rejection because of their dependency therein.

Claim 87 is indefinite because it recites the limitation "said nucleotide sequence". There is insufficient antecedent basis for this limitation because claim 12, from which claim 87 depends recites, "antisense nucleic acid". Appropriate correction is required.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode complemented by the inventor of carrying out his invention.

Claims 31, 45-69, 77-84, and 101 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a written description rejection.

Claims 31, 45-69, 77-84, and 101 are drawn to a method for screening a candidate compound for the ability to reduce cellular proliferation comprising providing a sublethal level of (1) an antisense complementary to a gene product encoded by a nucleic acid having at least 70% nucleotide sequence identity to a nucleic acid encoding a gene product whose expression is inhibited by SEQ ID NO:1463; (2) an antisense

complementary to a gene product having at least 25% amino acid identity to a gene product whose expression is inhibited by SEQ ID NO:1463; (3) an antisense complementary to a gene product encoded by a nucleic acid which hybridizes to SEQ ID NO:1463 under stringent conditions; (4) an antisense complementary to a gene product encoded by a nucleic acid which hybridizes to SEQ ID NO:1463 under moderate conditions; or (5) an antisense complementary to a gene product whose activity may be complemented by a gene product whose activity is inhibited by SEQ ID NO:1463.

The pending claims are drawn to a method for screening a candidate compound for the ability to reduce cellular proliferation. The issue is that the method of the claimed invention utilizes a sublethal level of an antisense complementary to a gene product, wherein the gene product is directed to both **identified** and **unidentified** gene products. For example, the specification teaches a method of utilizing a sublethal level of SEQ ID NO:1463, an antisense nucleic acid, directed to an identified gene product referred to as "yphC". However, the claims are so broad to include the utilization of an antisense complementary to a gene product whose activity may be complemented by a gene product whose activity is inhibited by SEQ ID NO:1463. Because adequate written description of a chemical invention also requires a precise definition, such as by structure, formula, chemical name, or physical properties, and not merely a wish or plan for obtaining the chemical invention claimed, and because one of skill in the art, reviewing the instant specification, would not be able to immediately envisage a representative sample of the members of such a broad genus, it is maintained that

Applicants are not in possession of the utilization of antisense complementary to a gene product whose activity may be complemented by a gene product whose activity is inhibited by SEQ ID NO:1463 that are heretofore undescribed.

See the January 5, 2001 (Vol. 66, No. 4, pages 1099-1111) Federal Register for the Guidelines for Examination of Patent Applications Under the 35 USC 112 ¶ 1, "Written Description" Requirement. These guidelines state: "[T]o satisfy the written description requirement, a patent specification must describe the claimed invention in sufficient detail that one skilled in the art can reasonably conclude that the inventor had possession of the claimed invention. An applicant shows possession of the claimed invention by describing the claimed invention with all of its limitations using such descriptive means as words, structures, figures, diagrams, and formulas that fully set forth the claimed invention. Possession may be shown in a variety of ways including description of an actual reduction to practice, or by showing that the invention was "ready for patenting" such as by the disclosure of drawings or structural chemical formulas that show that the invention was complete, or by describing distinguishing identifying characteristics sufficient to show that applicant was in possession of the claimed invention.

Vas-Cath Inc. v. Mahurkar, 19 USPQ2d 1111, makes clear that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the 'written description' inquiry, whatever is now claimed." (see page 1117). The specification does not "clearly allow persons of ordinary skill in the art to recognize that

[he or she] invention what is claimed." (See Vas-Cath at page 1116).

The specification does not provide written description for a method for screening a candidate compound for the ability to reduce cellular proliferation comprising providing a sublethal level of an antisense complementary to a gene product whose activity may be complemented by a gene product whose activity is inhibited by SEQ ID NO:1463. The breadth of this claim encompasses the utilization of *any* antisense complementary to a gene product whose activity may be complemented by a gene product whose activity is inhibited by SEQ ID NO:1463, which includes gene product sequences from any species, mutated sequences, polymorphic and allelic variants, splice variants, sequences that have an unspecified degree of identity (similarity, homology), known **or yet to be discovered**. Thus, the breadth of this claim also encompasses the utilization of antisense complementary to gene products whose sequences have not been identified or described by the instant specification.

Because the claims are so broad, a great deal of experimentation would be needed to identify, use, and discover antisense complementary to a gene product whose activity may be complemented by a gene product whose activity is inhibited by SEQ ID NO:1463 as recited in the instant claims. How would one skilled in the art identify a gene product whose activity may be complemented by a gene product whose activity is inhibited by SEQ ID NO:1463, particularly in the absence of any teaching by way of structure or reference to active domains or regions? The instant specification does not provide guidance as to which of the astronomical number of embodiments embraced by the claims might have the functional properties required in the claims.

Further, there are no working examples of antisense complementary to a gene product whose activity may be complemented by a gene product whose activity is inhibited by SEQ ID NO:1463 that carry out the functional properties required in the claims. With limited disclosure provided by the specification, the skilled artisan cannot envision those antisense complementary to a gene product whose activity may be complemented by a gene product whose activity is inhibited by SEQ ID NO:1463 as recited in the instant claims. Therefore, the use of antisense complementary to a gene product whose activity may be complemented by a gene product whose activity is inhibited by SEQ ID NO:1463 do not meet the written description provision of 35 U.S.C. 112, first paragraph.

Conclusions

Claims 12, 85, 86, and 89-96 are allowable. Claims 12, 85, 86, and 88-96 are allowable because the prior art does not teach or fairly suggest a method for screening a candidate compound for the ability to reduce cellular proliferation comprising (a) providing a sublethal level of an antisense nucleic acid complementary to a nucleic acid encoding a gene product in a cell to reduce the activity or amount of said gene product, thereby producing a sensitized cell, wherein said gene product's activity or amount is reduced by an antisense comprising SEQ ID NO:1463, provided that the cell is a prokaryotic organism; (b) contacting said sensitized cell with a compound and (c) determining the degree to degree to which said compound inhibits proliferation of said sensitized cell relative to a nonsensitized cell.

Claims 100, 103, and 104 are objected to because they contain nonelected subject matter, but would be allowable if rewritten to remove nonelected subject matter. Claims 100, 103, and 104 are considered to be free of the prior art since the prior art does not teach or fairly suggest a method for screening a candidate compound for the ability to reduce cellular proliferation comprising (a) providing a sublethal level of an antisense consisting of SEQ ID NO:1463, wherein said antisense reduces the activity or amount of a gene product required for cellular proliferation, thereby producing a sensitized cell, provided that said sensitized cell is a prokaryotic organism; (b) contacting said sensitized cell with a compound; and (c) determining the degree to which said compound inhibits proliferation of said sensitized cell relative to a nonsensitized cell.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Terra C. Gibbs whose telephone number is 571-272-0758. The examiner can normally be reached on 9 am - 5 pm M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Schultz can be reached on 571-272-0763. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only.

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tcg
December 10, 2006

/J. Schultz/
JAMES SCHULTZ, PH.D.
PRIMARY EXAMINER